

CLAIMS

1. A pharmaceutical aerosol formulation comprising particles of (a) formoterol or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof and (b) mometasone or a pharmaceutically acceptable salt, solvate, or physiologically functional derivative thereof dispersed in a propellant selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane and a mixture thereof, and a bulking agent having a mass median diameter of less than one micron.
2. A pharmaceutical aerosol formulation according to claim 1, wherein the formoterol is in the form of formoterol fumarate.
3. A pharmaceutical aerosol formulation according to claim 2, wherein the formoterol is in the form of formoterol fumarate dihydrate.
4. A pharmaceutical aerosol formulation any one of claims 1 to 3, wherein the mometasone is in the form of mometasone furoate.
5. A pharmaceutical aerosol formulation according to any one of claims 1 to 4, wherein the formoterol is present in an amount of about 0.06 to 0.60 mg per ml.
6. A pharmaceutical aerosol formulation according to any one of claims 1 to 5, wherein the mometasone is present in amount of about 0.5 to 15.0 mg per ml.
7. A pharmaceutical aerosol formulation according to any one of claims 1 to 6, wherein the bulking agent is selected from groups consisting of ascorbic acid, saccharides, polysaccharides, amino acids, organic and inorganic salts, urea and propylidone.
8. A pharmaceutical aerosol formulation according to claim 7, wherein the bulking agent is selected from lactose, DL-alanine, glucose, D-galactose, D(+)-trehalose dihydrate, sucrose, maltose, D(+)-raffinose pentahydrate, sodium saccharin, starches, modified celluloses, dextrans, glycine, sodium chloride, calcium carbonate, sodium tartrate and calcium lactate.

9. A pharmaceutical aerosol formulation according to claim 7 or claim 8, wherein the bulking agent is lactose.
10. A pharmaceutical aerosol formulation according to any one of claims 1 to 9, wherein the weight ratio of formoterol to bulking agent is in the range 1:0.1 to 1:30.
11. A pharmaceutical aerosol formulation according to any one of claims 1 to 10, wherein the bulking agent has a mass median diameter of not more than 300 nm.
12. A pharmaceutical aerosol formulation according to any one of claims 1 to 11, wherein the formulation further comprises a surfactant.
13. A pharmaceutical aerosol formulation according to any one of claims 1 to 12, wherein the formulation further comprises ethanol.
14. A pharmaceutical aerosol formulation according to claim 13, wherein ethanol is present in amount of from 0.1 to 5% by weight of the formulation.
15. A dispenser comprising an aerosol vial equipped with a dispensing valve, said aerosol vial containing a formulation according to any one of claims 1 to 14.
16. A dispenser according to claim 16, wherein an interior surface of the aerosol vial is coated with a fluorocarbon polymer.
17. A method of preparing a formulation according to claim 1, the method comprising the steps of (i) forming a slurry of bulking agent with a component of the formulation; (ii) subjecting the slurry to high pressure homogenization; and (iii) combining the resulting slurry with other components of the aerosol formulation.